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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,589	07/30/2001	Calc M. Halbleib	Pan Vera.017.01	2015

26191 7590 03/22/2004
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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/918,589

Applicant(s)

HALBLEIB ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species PPAR in the Paper submitted 7/25/2003 is acknowledged. The traversal is on the ground(s) that there is no undue burden to search the members of the nuclear hormone receptor superfamily. This is found persuasive, and the requirement for election of species is withdrawn.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

Reference C16 on the IDS of 1/13/2003 has been lined through because it is not in the correct format. The citation should include the author and publication date, pursuant to 37 CFR 1.98.

Claim Rejections - 35 USC § 112 second paragraph

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in the recitation of the term "derived from". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, peptides expressed from isolated mRNA or only sequences produced by digestion of proteins isolated from tissue, or if the claim encompasses all peptide sequences that bind to the receptor. Therefore, the metes and bounds of the claim are unclear.

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Claim 13 is vague and indefinite because it is not clear how the fluorescence emitting compound could consist of the AF-1 domain or DNA binding domain, since neither of these domains would bind the receptor. The metes and bounds of this claim cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10-12, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/05962 (Bolger et al.).

The Bolger reference teaches a method for measuring the competitive binding of molecule to steroid hormone receptors comprising mixing a fluorescent-emitting compound that binds the steroid hormone receptor in a solution, with or without a test compound, measuring the fluorescence polarization of the solution of the solution and comparing the fluorescence polarization of the solution inn the presence and absence of the compound to indicate any competitive interaction (Bolger at 4), thus claims 1 is anticipated. The Bolger reference teaches that compounds other than steroids may be used (Id. at 6 and 11), thus claims 3, 11 are anticipated. The Bolger reference teachers that ER may be used in the method (Id. at 9), thus claim 4 is anticipated. The Bolger reference teaches that the recombinant ER may be used (Id. at 10) thus claims 6-7 are anticipated. The compounds used in the method of Bolger are inherently fluorescent (Id. at 4) thus claim 10 is anticipated. Claim 12 is anticipated due to the indefinite nature of the term “derived from”, see rejection under 35 USC 112 second paragraph, *supra*. In

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the method of Bolger, more than one copy of the receptor will be present, thus claim 15 is anticipated. The Bolger reference teaches that the method may be carried out in a 96 or 384 well plate (Id. at 7), thus claim 14 is anticipated.

Claims 1-3, 5-6, 10-12, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/27365 (Lustig et al.)

The Lustig et al. reference teaches a method of screening for modulators of nuclear hormone receptor function comprising measuring the binding of a sensor polypeptide at sub-micromolar concentrations to a nuclear hormone receptor in the presence of a candidate agent (Lustig at 2). The sensor comprises a peptide with a receptor binding sequence and a fluorescent label, and the measurement is by fluorescent polarization assay (Id. at 5). The reference also teaches that the assay can be carried out with LXR (Id. at 2), thus claims 1-3, 10-11 are anticipated. Claim 12 is anticipated due to the indefinite nature of the term "derived from", see rejection under 35 USC 112 second paragraph, *supra*. The reference also teaches that ERR can be used in the assay (Id. At 4) thus claim 5 is anticipated. The reference also teaches that the method can be carried in a high-throughput screen, thus claim 14 is anticipated. Claim 15 is anticipated because more than one receptor will be present in the screen. The reference teaches there are a wide variety for producing the receptors (Id. at 3, thus claim 6 is anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/05962 (Bolger et al.) in view of U.S. Patent No. 6,054,295.

The claims are drawn to a method for measuring the competitive binding of molecule to steroid hormone receptors comprising mixing a fluorescent-emitting compound that binds the steroid hormone receptor in a solution, with or without a test compound, measuring the fluorescence polarization of the solution of the solution and comparing the fluorescence polarization of the solution in the presence and absence of the compound to indicate any competitive interaction, and further wherein the nuclear receptor is a fusion protein. The claims are unpatentable, as set forth in the rejection under 35 USC 102(b) over the Bolger reference, set forth *supra*. The Bolger reference does not teach fusion proteins of nuclear hormone receptors

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with GST. However, the '295 patent discloses fusion constructs expressing both full length nuclear receptors fused to GST coding sequences, as well as ligand binding domains of nuclear hormone receptors fused to GST ('295 at column 14 ,lines 5-20). Therefore it would have been obvious to one of skill in the art at the time the invention was made to practice a method of measuring the competitive binding of molecule to steroid hormone receptors comprising mixing a fluorescent-emitting compound that binds the steroid hormone receptor in a solution, with or without a test compound, measuring the fluorescence polarization of the solution of the solution and comparing the fluorescence polarization of the solution inn the presence and absence of the compound to indicate any competitive interaction, and further wherein the nuclear receptor is a fusion protein. The motivation and expectation of success are provided in the '295 patent which disclose that the fusion proteins are useful in assays to identify compounds which modulate wild type nuclear hormone receptors ('295 at column 14, lines 5-10).

Conclusion

No claim is allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.
Patent Examiner
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March 16, 2004